

QuikScreen® 5 Plus

With 4 Parameter Adulteration Strips

Instructions

INTENDED USE

The QuikScreen® 5 Plus is an immunochromatographic assay for rapid, qualitative detection of drug combinations and their principal metabolites in urine at specified cut-off concentrations. This drug combination is composed of the following drugs:

DRUG CLASS	SENSITIVITY
AMPHETAMINE	1000 ng/ml
COCAINE/BENZOYLECGONINE	300 ng/ml
MARIJUANA	50 ng/ml
OPIATES/MORPHINE	2000 ng/ml
PHENCYCLIDINE	25 ng/ml

An added feature to assess the integrity of the urine samples prior to drug testing, is a visual determination of *pH*, *Specific Gravity*, *NBP (Nitrite, Bleach, Pyridinium Chlorochromate)* and *Glutaraldehyde*. These adulteration strips are built into the test device which may provide information regarding urine sample tampering.

Note: The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION OF THE TEST

The QuikScreen® Plus is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening without the need of instrumentation. The method employs unique mixture of antibodies to selectively identify the drugs of abuse and their metabolites in test samples with a high degree of sensitivity.

Drug abuse remains a growing social and economical concern in many developed and developing countries throughout the world. The above stated drugs are among the most frequently abused illicit drugs, according to the U.S. Substance Abuse and Mental Health Services Administration. Opiates are among a class of heavily abused prescription drugs.

The sensitivity of the QuikScreen® Plus is set as required for the screening immunoassays of these drugs in the reference guidelines set by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Department of Health and Human Services.

PRINCIPLE OF THE TEST

The QuikScreen® Plus is a competitive binding immunoassay in which drug and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. By utilizing antibodies that are specific to different drug classes, the test permits independent, simultaneous detection of any of the drug combinations from a single sample. The approximate run time is 5 minutes.

In the assay procedure, urine mixes with labeled antibody-dye conjugate and migrates along a porous membrane. When the concentration of a given drug is below the detection limit of the test, unbound antibody-dye conjugate binds to antigen conjugate immobilized on the membrane, producing a rose-pink color band in the appropriate Test Zone for that drug. Conversely, when the drug level is at or above the detection limit, free drug competes with the immobilized antigen conjugate on the membrane by binding to antibody-dye conjugate, forming an antigen- antibody complex, preventing the development of a rose-pink color band.

Regardless of the drug levels in the sample, a rosepink-color band is produced in each Control Zone (top bands) by a parallel immunochemical reaction. These bands serve as built-in quality control measures by demonstrating antibody recognition, verifying that the reagents are chemically active.

Included in this device are the following 4-parameter adulteration strips to determine whether the urine sample is adulterated:

pH, *Specific Gravity*, *NBP (Nitrite, Bleach & Pyridinium Chlorochromate)* and *Creatinine* results of which can be achieved by comparing to the color chart provided.



REAGENTS AND MATERIALS PROVIDED

1. Test Devices Contains dye-conjugated antibody and immobilized antigen in protein matrix with sodium azide.
2. Test Instructions Cat. # PI-65505-7
3. Color Chart Cat. # COL-007

Optional:

4. Negative Control I Contains buffered protein solution with sodium azide. Cat. # 4010N
5. Amphetamine Positive Control Contains AMP at 3000 ng/ml in a buffered protein solution with sodium azide. Cat. # 11120-BP
6. Cocaine Positive Control Contains BEG at 1000 ng/ml in a buffered protein solution with sodium azide. Cat. # 12000-BP
7. Marijuana Positive Control Contains THC at 150 ng/ml in a buffered solution with sodium azide. Cat. # 13020P
8. Opiates Positive Control Contains MOR at 5000 ng/ml in a buffered protein solution with sodium azide. Cat. # 11220-BP
9. PCP Positive Control Contains PCP at 100 ng/ml in a buffered protein solution with sodium azide. Cat. # 14020P

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer.
2. Specimen collection containers.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic and professional use only.
2. Do not use the test device beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
4. Visually inspect the foil package to insure it is intact. If the package is not intact, the integrity of the device might be compromised.

STORAGE AND STABILITY

Store test kit below 28°C; **do not freeze**. If stored at 2°-8°C, allow the test kit to reach room temperature (15°-28°C) before performing the test. Refer to the expiration date for stability.

QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

The QuikScreen® Plus also provides internal control to determine adulteration of the urine sample in the form of 4 reagent strips, to test for *pH*, *Specific Gravity*, *NBP (nitrite, bleach, pyridinium chlorochromate)* and Creatinine on urine samples submitted for drugs of abuse testing.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine specimens should be collected directly into the cup. The QuikScreen® Plus device employs a **thermal strip which should be checked immediately** after collection to validate urine specimen. SAMHSA regulations specify that any temperature below 90.5°F must be considered adulterated. No additives or preservatives are required. **Note: Urine specimens can be transferred from a urine collection container into the QuikScreen® Plus test cup, if necessary.**

TEST PROCEDURE

1. Do not break the seal of the pouch until ready to begin testing.
2. Remove the Test Cup from the foil pouch.
3. Collect urine specimen directly into the Test Cup. Insure that the sample amount meets the minimum level as indicated on the side of the Test Cup.
4. **Wait 1 minute and immediately read the adulteration strips for pH and Specific Gravity. At 5 minutes read the adulteration strips for creatinine and NBP(nitrite, bleach, pyridinium chlorochromate).** Obtain results by comparing them to the color chart provided. Color comparison must be performed under a good light source. If results show that the urine sample was **adulterated, do not read the drug test result.**
5. If urine sample is found to be **unadulterated, read the drug test results.**

NOTE: The results must be interpreted at five minutes, except for pH and Specific Gravity. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

Adulteration Strips

Results are obtained by direct comparison of the reacted strip with the color chart provided, similar to the illustration below. Adulterated urine sample will show result colors under the "Abnormal" block colors of the chart. Unadulterated urine sample will show the strip colors similar to the "Normal" block colors of the color chart.

Based on the information gathered from a review of current clinical and forensic toxicology literature and recommendations made by the U.S. Substance Abuse and Mental Health Services Administration's Drug Testing Advisory Board, a specimen is defined to be:

- a. **Dilute** if the Specific Gravity is <1.003 , unless the criteria for a *substituted* specimen are met.
- b. **Dilute** if the creatinine is < 20 mg/dl unless the criteria for a *substituted* specimen are met.
- c. **Adulterated** if the Nitrite concentration is >0.5 mg/ml.
- d. **Adulterated** if the pH is < 4 or > 8 .
- e. **Adulterated** if an exogenous substance (i.e., a substance which is not a normal constituent of urine such as glutaraldehyde, bleach, pyridinium chlorochromate) or an endogenous substance at a higher concentration than normal physiological concentration is present in the specimen.

DEVICE FEATURE:

Included in this device are the following 4-parameter adulteration strips to determine whether the urine sample is adulterated:

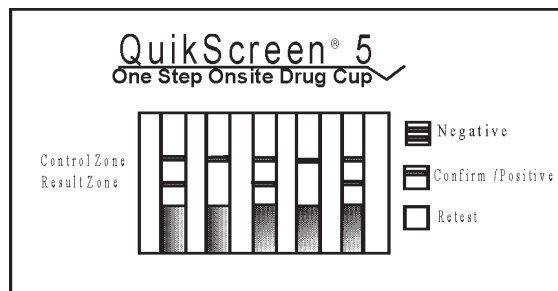
pH test is based on multiple indicators which give a broad range of colors covering the entire urinary pH range. Colors range from maroon to pinkish-red through orange and dark green.

Creatinine interacts with a creatinine indicator in an alkaline medium and forms an orange-red complex. The color intensity is directly proportional to the concentration of creatinine when compared visually to the color chart to obtain result.

Specific Gravity (SG) is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark green or blue green in urine of low ionic concentration to green or yellow-green in urine of higher ionic concentration.

Nitrite, Bleach and Pyridinium Chlorochromate (NBP) test is based on the development of colors ranging from cream, for negative reading, to a positive color of green, brownish green, or brown when the chromogen is oxidized by nitrite, bleach, or pyridinium chlorochromate.

INTERPRETATION OF RESULTS (CONT'D.)



Confirm (Positive): A *rose-pink* band is visible in each control zone (top band). No color band appearing in the appropriate test zone (bottom band) indicates a preliminary positive result for the corresponding drug of that specific test zone. Send urine specimen to a certified laboratory for confirmation.

Negative: A *rose-pink* band is visible in each control zone and the appropriate test zone, indicating that the concentration of the corresponding drug of that specific test zone is below the detection limit of the test.

Retest: If a color band is not visible in each of the control zones, the test is invalid. Another test should be run to re-evaluate the specimen.

Note: There is no meaning attributed to line color intensity or width.

LIMITATIONS OF THE TEST

1. This product is designed to be used for the detection of drugs of abuse and their metabolites in human urine only.
2. Although the test is very accurate, there is the possibility false results will occur due to the presence of interfering substances in the specimen sample.
3. The test is a qualitative screening assay and is not suggested for quantitative determination of drug levels in urine, or the level of intoxication.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, can cause erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity.** The QuikScreen® 5 Plus Test detects drugs of abuse and their major metabolites in urine at concentrations equal to or greater than the cut-off level for the specific drug, which is suggested by the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) for the immunoassay method.
2. **Specificity.** A study was conducted with the QuikScreen® 5 Plus Test to determine the cross-reactivity of drug-related compounds with the test. Substances listed in **Table I** produced results approximately equivalent to the cutoff levels. A separate study was conducted to determine the cross-reactivity of non-related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross reactivity was detected with the substances listed in **Table II**.

Table I: Concentrations of drug-related compounds showing positive response approximately equivalent to the cut-off set for the test:

The following Amphetamine-related substances yield positive results for Amphetamine at 1000 ng/ml cut-off:

d-Amphetamine	1000 ng/ml	β -Phenylethylamine	180,000 ng/ml
l-Amphetamine	50,000 ng/ml	Tyramine	120,000 ng/ml
d,l-Amphetamine	1,250 ng/ml	(\pm) 3,4-Methylenedioxyamphetamine (MDA)	500 ng/ml
Deoxyephedrine	1,000,000 ng/ml	Pseudoephedrine	5,000,000 ng/ml
Phentermine	50,000 ng/ml	Ephedrine	10,000,000 ng/ml
(\pm)Phenylpropanolamine	50,000 ng/ml		

The following Cocaine-related substances yield positive results for Cocaine

at 300 ng/ml Cut-Off Level

Benzoylcegonine	300 ng/ml
Cocaine	300 ng/ml
Isoxsuprine	2,500 ng/ml

The following Marijuana-related substances yield positive results for Marijuana at 50 ng/ml cut-off:

11-Nor- Δ^8 -THC-9-COOH	50 ng/ml
11-Nor- Δ^9 -THC-9-COOH	50 ng/ml
Δ^8 -THC	1 μ g/ml
Δ^9 -THC	4 μ g/ml
Cannabinol	10 μ g/ml
11-Hydroxy- Δ^9 -THC	10 μ g/ml

The following Opiates-related substances yield a positive result for Opiates at 2000 ng/ml Cut-Off Level:

Morphine	2,000 ng/ml	Levorphanol	6,000 ng/ml
Morphine-3-β-D-Glucuronide	2,000 ng/ml	Naloxone	10,000 ng/ml
Codeine	2,000 ng/ml	Thebaine	15,000 ng/ml
Heroin	2,000 ng/ml	Imipramine	500,000 ng/ml
Norcodeine	20,000 ng/ml	Atropine	1,000,000 ng/ml
Hydrocodone	5,000 ng/ml	Meperidine	1,000,000 ng/ml
Hydromorphone	2,000 ng/ml	Ranitidine	1,000,000 ng/ml
Oxycodone	100,000 ng/ml		

The following Phencyclidine (PCP)-related substances yield positive results for PCP at 25 ng/ml Cut-Off:

n-Acetylprocainamide	10,000 ng/ml
Codeine	5,000 ng/ml
p-Hydroxymethamphetamine	50,000 ng/ml
Thebaine	10,000 ng/ml
1-(1-Phenylcyclohexyl)morphine	600 ng/ml
N,N-Diethyl-1-phenyl-cyclohexylamine	2.0 ng/ml
1-[1-(2-Thienyl)cyclohexyl]morphine	200 ng/ml
Phencyclidine	25 ng/ml
1-(4-Hydroxypiperidino) phenylcyclohexane	550 ng/ml
1-(1-Phenylcyclohexyl) pyrrolidine	200 ng/ml
4-Phenyl-4-piperidino cyclohexanol	60 ng/ml
1-[1-(2-Thienyl)-cyclohexyl] piperidine	30 ng/ml
1-[1-(2-Thienyl)-cyclohexyl] pyrrolidine	600 ng/ml

Table II: Compounds tested and found not to cross-react with the test at a specified concentration amount in urine.

The following compounds do not cross-react with (1000 ng/ml cut-off) Amphetamine at a 100 µg/ml concentration in urine:

Acetaminophen	5,5-Diphenylhydantoin	Morphine Sulfate
Acetylsalicylic Acid	Doxylamine	Oxazepam
Amikacin	Ecgonine ·HCl	Oxycodone
Amitriptyline	Ecgonine Methyl Ester	Phendimetrazine
Ampicillin, Sodium Salt	Glucose	Penicillin G
Arterenol	Histamine	Pentobarbital
Aspartame	Hydrochlorothiazide	d-Propoxyphene
Atropine	Hydrocodone	1-Propanol
Benzoic Acid	Hydromorphone	Phencyclidine ·HCl
Benzoyllecgonine	Indomethacin	Phenobarbital
Caffeine	Ketoprofen	l-Phenylephrine
(+) Chlorpheniramine Maleate	Levorphanol	Quinine
(±) Chlorpheniramine Maleate	Δ ⁹ -THC	Ranitidine
Chlorpromazine ·HCl	(-)11-Nor-Δ ⁹ -THC-9-COOH	Sodium Salicylate
Cimetidine	Meperidine	Tetracycline
Codeine	Methylphenidate	Tetrahydrozoline
Dextromethorphan ·HBr	Methadone	Theophylline
Diazepam	Methaqualone	Thioridazine
	Morphine-3-β-D-Glucuronide	Trifluoperazine
		Tryptophan

The following compounds do not cross-react with (300 ng/ml cut-off) Cocaine at a 100 µg/ml concentration in urine:

Acetaminophen	Ecgonine ·HCl	Phendimetrazine
Acetylsalicylic Acid	Ecgonine Methyl Ester	Penicillin G
Amikacin	Glucose	Pentobarbital
Amitriptyline	Histamine	D-Propoxyphene
Ampicillin	Hydrochlorothiazide	1-Propanol
Arterenol	Hydrocodone	Phencyclidine
Aspartame	Hydromorphone	Phenobarbital
Atropine Sulfate	Indomethacin	Phentermine
Benzoic Acid	Ketoprofen	Phenylpropanolamine
Caffeine	Levorphanol	l-Phenylephrine
Chlorpheniramine	Δ ⁹ -THC	Quinine
Chlorpromazine ·HCl	11-Nor-Δ ⁹ -THC-9-COOH	Ranitidine
Cimetidine	Meperidine	Sodium Salicylate
Codeine	Methylphenidate	Tetracycline
Deoxyephedrine	Methadone	Tetrahydrozoline
Dextromethorphan	Methaqualone	Theophylline
Diazepam	Morphine-3-β-D-Glucuronide	Thioridazine
Diethylpropion	Morphine Sulfate	Trifluoperazine
5,5-Diphenylhydantoin	Oxazepam	Tryptophan
Doxylamine	Oxycodone	

The following compounds do not cross-react with (50 ng/ml cut-off) Marijuana at a 100 µg/ml concentration in urine:

Acetaminophen	Digitoxin	Meperidine
4-Acetamidophenol	Digoxin	Methadone
Acetylsalicylic Acid	Ecgonine ·HCl	Methaqualone
Amikacin	Ecgonine Methyl Ester	Naloxone
Ampicillin	Ephedrine	Neomycin
d,l-Amphetamine	Epinephrine	Niacinamide
Amitriptyline	Gentisic Acid	Oxazepam
Arterenol	Glucose	Perphenazine
Aspartame	Guaiacal	Penicillin G
Atropine Sulfate	Glyceryl Ether	Phencyclidine
Benzoic Acid	Histamine	Phenobarbital
Benzoyllecgonine	Hydrochlorothiazide	α-Phenylethylamine
Caffeine	Hydrocodone	Phenylpropanolamine
Camphor	Hydromorphone	Promethazine
Chloroquine	Homatropine	Pseudoephedrine
Chlorpheniramine	Imipramine	Ranitidine
Chlorpromazine ·HCl	Isoproterenol	Salicylic Acid
Cocaine ·HCl	Ketamine	Secobarbital
Cocaine	Lidocaine	Tetracycline
Cimetidine	Methylphenidate	Tetrahydrozoline
Cortisone	Morphine	Theophylline
Deoxyephedrine	Morphine-3-β-D-Glucuronide	Thioridazine
Dextromethorphan	Morphine Sulfate	Trifluoperazine
Diazepam	d-Methamphetamine	Tryptophan

The following compounds do not cross-react with (2000 ng/ml cut-off) Opiates at a 100 µg/ml concentration in urine:

Acetaminophen	5,5-Diphenylhydantoin	Pentobarbital
Acetylsalicylic Acid	Doxylamine	d-Propoxyphene
Amikacin	Ecgonine ·HCl	1-Propanol
Amitriptyline	Ecgonine Methyl Ester	Phencyclidine
Ampicillin	Glucose	Phenobarbital
Arterenol	Histamine	Phentermine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Benzoic Acid	Indomethacin	l-Phenylephrine
Benzoyllecgonine ·HCl	Ketoprofen	Quinine
Caffeine	Δ ⁹ -THC	Sodium Salicylate
Chlorpheniramine	11-Nor-Δ ⁹ -THC-9-COOH	Tetracycline
Chlorpromazine ·HCl	Methylphenidate	Tetrahydrozoline
Cimetidine	Methadone	Theophylline
Deoxyephedrine	Methaqualone	Thioridazine
Dextromethorphan	Oxazepam	Trifluoperazine
Diazepam	Phendimetrazine	Tryptophan
Diethylpropion	Penicillin G	

The following compounds do not cross-react with (25 ng/ml cut-off) Phencyclidine at a 100 µg/ml concentration:

Acetaminophen	Ecgonine ·HCl	Phendimetrazine
Acetylsalicylic Acid	Ecgonine Methyl Ester	Penicillin G
Amikacin	Glucose	d-Propoxyphene
Amitriptyline	Histamine	1-Propanol
Ampicillin	Hydrocodone	Phenobarbital
Arterenol	Hydromorphone	Phentermine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Atropine Sulfate	Indomethacin	l-Phenylephrine
Benzoic Acid	Ketoprofen	Quinine
Benzoyllecgonine ·HCl	Levorphanol	Ranitidine
Caffeine	Δ ⁹ -THC	Sodium Salicylate
Chlorpheniramine	11-Nor-Δ ⁹ -THC-9-COOH	Tetracycline
Chlorpromazine ·HCl	Meperidine	Tetrahydrozoline
Cimetidine	Methylphenidate	Theophylline
Deoxyephedrine	Methadone	Thioridazine
Dextromethorphan	Methaqualone	Trifluoperazine
Diazepam	Morphine-3-β-D-Glucuronide	Tryptophan
Diethylpropion	Morphine Sulfate	
5,5-Diphenylhydantoin	Oxazepam	
Doxylamine	Oxycodone	

3. **Accuracy:** The accuracy of the QuikScreen® 5 Test was tested in a clinical trial of urine samples submitted to a SAMHSA certified laboratory. The laboratory used EMIT II as their screening procedure. All positive samples by either screening method were confirmed by GC/MS. The results are summarized as follows:

3.1 AMPHETAMINE (AMP) 1000ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	205	0
QuikScreen® Negative	0	237

When compared to EMIT II the relative sensitivity between positive samples was 100% . The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 100%.

3.2 COCAINE (BEG) 300 ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	165	2
QuikScreen® Negative	0	151

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 98.69%. The concordance of the combined data with respect to EMIT II was 99.37%.

3.3 MARIJUANA (THC) 50 ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	52	0
QuikScreen® Negative	0	513

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 100%.

3.4 OPIATES (OPI) 2000 ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	195	0
QuikScreen® Negative	0	500

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 100%.

3.5 PHENCYCLIDINE (PCP) 25ng/ml Cut-Off Level

	Syva EMIT II Positive	Syva EMIT II Negative
QuikScreen® Positive	14	0
QuikScreen® Negative	0	551

When compared to EMIT II the relative sensitivity between positive samples was 100%. The relative specificity between negative samples was 100%. The concordance of the combined data with respect to EMIT II was 100%.

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